

LISTING OF CLAIMS READABLE ON ELECTED SPECIES

1. (currently amended) A process for delivering a protein or peptide to an extravascular cell in a mammalian target tissue in vivo comprising: inserting an injection solution containing the protein or peptide into the lumen of an efferent or afferent vessel of the target tissue wherein the inserting of the injection solution results in an increase in pressure in a vein of the target tissue of 10 mm Hg or greater ~~volume of the injection solution and the rate of injection solution insertion cause transient increased vascular permeability in the target tissue, increased extravascular fluid volume within the target tissue, swelling of the target tissue, and extravasation of the protein or peptide via the increased vascular permeability, thereby~~ resulting in delivery of the protein or peptide to the extravascular cell.
2. (original) The process of claim 1 wherein fluid flow out of the target tissue is occluded.
4. (previously presented) The process of claim 1 wherein the protein or peptide consists of a biologically active protein or peptide.
6. (previously presented) The process of claim 5 wherein the protein or peptide is greater than 5 kDa.
7. (previously presented) The process of claim 6 wherein the protein or peptide is greater than 30 kDa.
8. (previously presented) The process of claim 7 wherein the protein or peptide is greater than 500 kDa.
12. (previously presented) The process of claim 1 wherein the protein or peptide consists of a therapeutic molecule.
13. (previously presented) The process of claim 1 wherein the protein or peptide is in a complex.
14. (previously presented) The process of claim 1 wherein the injection solution contains a compound that increases vessel permeability.
15. (original) The process of claim 14 wherein the compound consists of a vasodilator.
16. (original) The process of claim 1 wherein the cell consists of a liver cell.
17. (original) The process of claim 16 wherein the liver cell consists of a hepatocyte.
18. (original) The process of claim 1 wherein the cell consists of a skeletal muscle cell.
19. (original) The process of claim 1 wherein the cell consists of a heart muscle cell.

20. (original) The process of claim 1 wherein the cell consists of a prostate cell.
21. (original) The process of claim 1 wherein the vessel consists of a blood vessel.
22. (original) The process of claim 21 wherein the blood vessel consists of an artery.
23. (original) The process of claim 21 wherein the blood vessel consists of a vein.
24. (original) The process of claim 1 wherein the vessel consists of a bile duct.
25. (original) The process of claim 1 wherein the injection solution contains less than 20 mM salt.
26. (original) The process of claim 25 wherein the injection solution contains less than 5 mM salt.
27. (original) The process of claim 1 wherein the injection solution contains zwitterions.
29. (original) The process of claim 1 wherein the injection solution is hypertonic.
30. (currently amended) A process for delivering a protein or peptide to an extravascular in vivo mammalian cell in a target tissue comprising: rapidly inserting a sufficient volume of injection solution containing the protein or peptide into the lumen of an efferent or afferent vessel of the target tissue and impeding fluid flow away from the tissue during the injection wherein the inserting of the injection solution results in an increase in pressure in a vein of the target tissue of 10 mm Hg or greater ~~such that extravascular fluid volume in the tissue is transiently increased, thereby~~ resulting in swelling of the target tissue, increased vascular permeability in the target tissue, extravasation of the protein or peptide and delivery of the protein or peptide to the extravascular mammalian cell in the tissue.

REMARKS

Rejection of the claims under 35 USC §102:

Claims 1-2, 4, 6-8, 12-27, and 29 have been rejected under 35 U.S.C. 102(b) as being anticipated by Twist et al. (U.S. Patent 5,633,230). Applicants have amended the claims to obviate the rejection. Specifically, Applicants have amended the claims to recite "inserting of the injection solution results in an increase in pressure in a vein of the target tissue of 10 mm Hg or greater". Support for the amendment can be found in the specification on page 5 lines 20-22, page 10 line 29 to page 11 line 2, page 53 lines 15-26. As shown in Applicants previously filed Declaration under 37 C.F.R. 1.132, injection of a solution as performed by Twist et al. would fail to cause an increase in venous pressure. Applicants request reconsideration of the rejection.

Claims 1-2, 4, 6-8, 12-27, 29, and 30 have been rejected under 35 U.S.C. 102(b) as being anticipated by Goddard (U.S. Patent 5,602,094). Applicants have amended the claims as described above to obviate the rejection. Applicants request reconsideration of the rejection.

Double Patenting:

Claims 1-2, 4, 6-8, 12-27, 29, and 30 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 14 of U.S. Patent 7,144,869 in view of Rosenberg et al. (US 2002/0064520). With this amendment, Applicants have filed a terminal disclaimer to overcome the rejection.

The Examiner's rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1-2 and 4, 6-8, and 12-30 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being
transmitted to the USPTO on this date: 03/23/2009.

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